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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/555,544	11/04/2005	Yoshihiro Ohmiya	SAEG129.016APC	9022

20995 7590 01/15/2008  
KNOBBE MARTENS OLSON & BEAR LLP  
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IRVINE, CA 92614

EXAMINER
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PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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01/15/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com  
eOAPilot@kmob.com

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,544	<b>Applicant(s)</b> OHMIYA ET AL.	
	<b>Examiner</b> Rebecca E. Prouty	<b>Art Unit</b> 1652	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 is/are pending in the application.  
     4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

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Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 2, 7, 9, 10, 12, and 13, drawn to polynucleotides encoding a red-emitting rail road worm luciferase (SEQ ID NO:7) and vectors and host cells comprising said polynucleotides.

Group II, claim(s) 1, 2, 7, 9, 10, 12, and 13, drawn to polynucleotides encoding a green-emitting rail road worm luciferase (SEQ ID NO:16) and vectors and host cells comprising said polynucleotides.

Group III, claim(s) 1, 2, 7, 9, 10, 12, and 13, drawn to polynucleotides encoding a green-emitting *Rhagophthalmus obha* luciferase (SEQ ID NO:10) and vectors and host cells comprising said polynucleotides.

Group IV, claim(s) 1, 2, 7, 9, 10, 12, and 13, drawn to polynucleotides encoding a orange-emitting *Rhagophthalmus obha* luciferase (SEQ ID NO:11) and vectors and host cells comprising said polynucleotides.

Group V, claim(s) 3, drawn to methods of enabling expression of a luciferase in mammalian cells.

Group VI, claim(s) 5 and 6, drawn to a luciferase of SEQ ID NO:4 and variants thereof.

Group VII, claim(s) 7, 9-16, 22, and 23, drawn to a gene construct comprising 2 luciferases which emit light whose wavelength does not substantially depend on a determining condition and cells comprising said construct.

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Group VIII, claim(s) 7-19, 22, and 23, drawn to a gene construct comprising 3 luciferases which emit light whose wavelength does not substantially depend on a determining condition and cells comprising said construct.

Group IX, claim(s) 7-23, drawn to a gene construct comprising 4 luciferases which emit light whose wavelength does not substantially depend on a determining condition and cells comprising said construct.

Group X, claim(s) 24, drawn to methods of screening drugs.

Group XI, claim(s) 25-27, drawn to methods of multiply determining transcription activity of multiple promoters before and after a change of culture environment.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the only shared technical feature of Groups I-XI appears to be the presence of at least one luciferase which emits light whose wavelength does not substantially depend on a determining condition. However this does not constitute a special technical feature as Nawotka et al. (WO 2003/016839) discloses red photoprotein derived from railroad worm, having stable expression in mammalian cells the luciferase capable of emitting light whose emission wavelength is substantially not dependent upon determination conditions.

This application contains claims directed to more than one species of the generic invention of Groups VII-IX. These species are deemed to lack unity of invention because they are

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not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are constructs comprising different combinations of 2, 3, or 4 luciferase genes linked to 2, 3, or 4 distinct types of promoters (from the group of constantly expressed promoters, toxicity assessing promoters, psuedopromoters, promoters subjected to assessment, and promoters of a protein which accepts an external/exogenous factor, see claims 18-23).

Applicant is required, in reply to this action, to elect a single combination of specific luciferase genes commensurate in number with the election of the group (i.e., 2 specific genes if Group VII is elected, 3 specific luciferase genes if Group VIII is elected and 4 specific luciferase genes if Group IX is elected) and to elect a single combination of types of promoters commensurate in number with the election of the group (i.e., 2 types of promoters if Group VII is elected, 3 types of promoters if Group VIII is elected and 4 types of promoters if Group IX is elected) to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is

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allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Currently each of claims 18-23 recite specific species and Claims 7-17 are generic with regard to promoter combinations while all claims are generic with regard to luciferase gene combinations.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the only shared technical feature among the different species is that they all constitute combinations of different luciferase genes with distinct wavelengths of emitted light or different combinations of different promoters with different properties. However, this is not a special technical feature within the meaning of PCT Rule 13.2 as Contag et. al. (US Patent 6,495,355) describes use

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of combinations of luciferase genes with distinct wavelengths of light emission as well as fusing these luciferase genes to distinct combinations of promoters.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/  
Primary Examiner  
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